LETTERS TO THE EDITOR

Regarding "Limb-salvage angioplasty in vascular surgery practice"

We read with great interest the article on infrainguinal angioplasty for limb salvage by Tefera et al.[1] Although distal bypasses are considered as the most durable revascularization procedures for patients with chronic critical limb ischemia secondary to infrapopliteal occlusive disease,[2] there is increasing evidence of usefulness of endovascular techniques. We would like to make some necessary comments regarding this study, which adds to the growing literature on infrapopliteal angioplasty.

1. There is frequently a multisegmental or multivessel involvement (ie, two or three crural arteries) in these patients.[3] Did the authors consider recanalization of one patent vessel as a technical success, or was an attempt made to open up more than one vessel in the leg?
2. Complications such as major dissection or plaque disruption with subsequent thrombosis may result in an acute deterioration in the severity of ischemia, especially so if the major collaterals are involved. As the "bail-out" option of stent is not applicable to these vessels, what was the treatment protocol for such events?
3. Was surgical revascularization needed on an emergent basis? This would mandate a good surgical backup for endovascular procedures.
4. We agree with the authors that ankle-brachial index measurements may not be helpful in more than 50% of patients during the follow-up period. What was their method of evaluation in patients with non-compressible leg vessels?

We remain enthusiastic about this procedure and, like others,[4,5] consider infrapopliteal angioplasty to be the initial choice for management of critical limb ischemia. We are a group of vascular surgeons who realized the magnitude of endovascular options more than 14 years ago and use subintimal angioplasty especially in diabetic patients with significant comorbidities. Long-term patency rates may not be as high or comparable with surgical revascularization, but if relief of rest pain wound healing and limb salvage can be achieved by a nonsurgical, minimally invasive option, the procedure has a good future.

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Reply

We agree with Dr Parakh in that percutaneous infrainguinal revascularization is an important adjunct and that there is growing evidence about its usefulness in a selected group of patients. Short of good prospective studies, however, some important questions (such as durability) may not be easily answered. Dr Parakh raises some important questions.

1. We attempted to revascularize more than one crural vessel. Unfortunately, we could not make conclusive statements because some of our data were incomplete; however, recanalizing one vessel was considered a technical success. The question remains whether revascularizing more than one vessel can have better clinical success.
2. We had only one case in which thrombosis with clinical deterioration occurred, and this patient was treated with an overnight thrombolysis. As a bailout very recently (since the publication of this article), we have used small coronary stent.
3. We are a group of vascular surgeons and do not need any backup. Overall, complications requiring emergency operation are rare. In our series, no case needed emergency revascularization.
4. All patients are followed up clinically for resolution of symptoms such as rest pain, healing of wounds, or toe amputation sites. Superficial femoral artery lesions can be followed up by duplex ultrasonography. We are currently evaluating tissue oxygen tension on the dorsum of the foot to quantify improvements in oxygenation.

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Regarding "Lifeline registry of endovascular aneurysm repair: Long-term primary outcome measures"

I read with interest the results of long-term follow-up of patients in the Lifeline Registry of endovascular aneurysm repair (EVAR; J Vasc Surg 2005;42:1-10) and take issue with the authors' conclusion that EVAR is an effective and durable treatment for infrarenal aortic aneurysms. This conclusion is based on a low risk of aneurysm rupture and aneurysm-related death and a low surgical conversion rate. However, most EVARs were performed in patients with small aneurysms (1040 patients had aneurysms <5.5 cm in diameter), and it is known that open surgery does not confer a survival advantage for at least 8 years when such patients are compared with those assigned to aneurysm surveillance.[1] Although the natural history of small aneurysms remains uncertain, reports of rupture incidence for aneurysms smaller than 5 cm range from 0% at 5 years to 1% per year.[2,3] Unlike open surgery, in which the diseased vessel is replaced by a prosthetic graft, EVAR allows

the aneurysm wall to remain intact, and so the absence of rupture in EVAR patients, particularly those with small aneurysms, does not necessarily reflect graft durability or effectiveness. Reports of loss of the survival advantage conferred by EVAR when compared with open repair after 1 year of follow-up,[4] as well as the present study's finding that preoperative aneurysm size was predictive of rupture after EVAR, do not equate with graft durability. Indeed, stent fractures have been reported in 71% of for-cause explanted grafts and in 31% of incidentally explanted grafts.[5]

Although the need for secondary intervention in 18.28% of EVAR patients reflects on the effectiveness of the grafts, as well as on the skill required for their successful deployment, late secondary intervention in 2.7% of EVAR patients must be assumed to relate to stent graft failure over time, unless the authors state otherwise. This is at least as relevant a measure of graft durability as freedom from rupture. Eighteen aneurysm ruptures were reported in the EVAR group, and 8 aneurysm-related deaths were reported between years 1 and 6. A total of 34% of the EVAR group died during 5 years of follow-up, and further information on causes of death would be of interest. Classification of cause of death as verified, probable, or indeterminate, as recommended by reporting standards for aortic EVAR,[6] is not provided.

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Reply

Dr Manning takes issue with our conclusion that endovascular aneurysm repair (EVAR) is an effective and durable treatment of infrarenal aortic aneurysms because the conclusion is based on a low aneurysm rupture and aneurysm-related death rate and a low surgical conversion rate. However, prevention of aneurysm rupture and death from rupture is precisely why aortic aneurysms are treated. Therefore, the effectiveness and durability of EVAR in achieving these objectives must be viewed as the primary outcome measures. The Lifeline Registry data show that EVAR was effective in preventing aneurysm rupture in 99% of patients over a 6-year follow-up period. Similarly, EVAR was effective in preventing aneurysm-related death in 98% of patients, with no diminution of effectiveness over the 6-year follow-up period.[1] Although avoiding "surgical conversion"—or open surgical repair—is not a primary objective of aneurysm treatment per se, it is an objective of EVAR. Thus, the low surgical conversion rate reported by the Lifeline Registry must be viewed as evidence of the effectiveness and durability of EVAR in achieving the objective of avoiding open surgical repair. In this regard, it should be noted that the surveillance strategy for small aneurysms to which Dr Manning refers[2] was not entirely effective in preventing aneurysm rupture and death, because 1% of small aneurysms ruptured each year despite close surveillance and early treatment, if needed. Furthermore, the mortality rate for rupture was very high (90%): 11% of all deaths in the surveillance group were due to aneurysm rupture. Surveillance also was not a durable strategy in the UK small aneurysm trial, because 74% of patients in the surveillance group were treated with open surgery over an 8-year follow-up period.[2]

With regard to reports of a loss of EVAR's early survival advantage over open surgery after 1 year, no information on graft durability was provided.[3] Indeed, the use of all-cause mortality as the primary end point in these trials may obscure information related to the long-term durability of each aneurysm treatment strategy, because most deaths were due to non–aneurysm-related causes. In the prospective, randomized EVAR-1 trial, the reduction in the aneurysm-related death rate after EVAR (4%) remained lower than that after open surgery (7%) at 4 years ($P = .04$).[4] Similarly, there was a persistent low aneurysm-related death rate after EVAR in the Lifeline Registry (2% at 6 years). The threefold reduction in perioperative mortality which was demonstrated in the prospective randomized trials,[3,4] along with the reduced morbidity and more rapid recovery after EVAR, is a significant advantage to the patient despite subsequent late death from unrelated causes.

The Lifeline Registry report was focused on the primary outcome measures of EVAR as a treatment strategy and not on the specifics of individual device durability. As Dr Manning indicates, adverse events and endograft device failures can occur after EVAR. After 5 years, 22% of patients in the Lifeline Registry had undergone a secondary interventional procedure, and 5% had undergone surgical conversion. Nonetheless, the long-term primary outcome measures remained stable, with no suggestion of an increasing aneurysm rupture or aneurysm-related death rate over time, and open surgical repair had been avoided in 95% of patients. Thus, EVAR can be viewed as an effective and durable treatment strategy, within the 6-year time frame of the study, provided that patients are monitored and secondary treatments are performed when needed.

Christopher K. Zarins, MD, on behalf of the Lifeline Registry of EVAR Publications Committee

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